

FDA Regulation of Lead in Food

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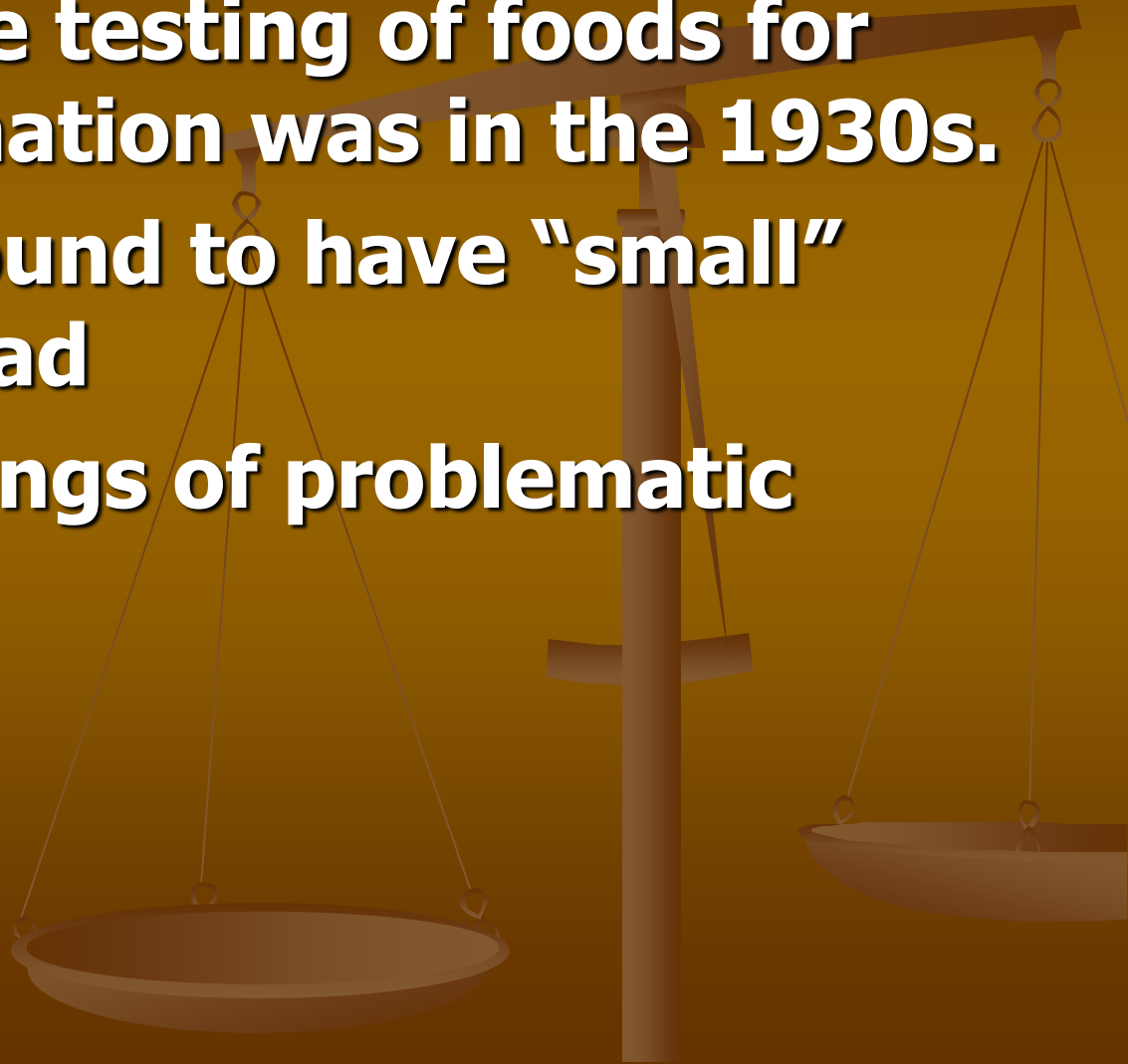


FDA's Early History of Regulation of Lead in Food

- **FDA activities to control lead in food trace back to early 1900s.**
 - **1908 Green coffee colored with lead chromate seized**
- **The major concern thru WWII was use of lead arsenate spray on apple orchards for insect control.**
- **Apples were washed to remove Pb, As residues, FDA extensively monitored apple products thru 1940s and enforced tolerances for Pb, As.**

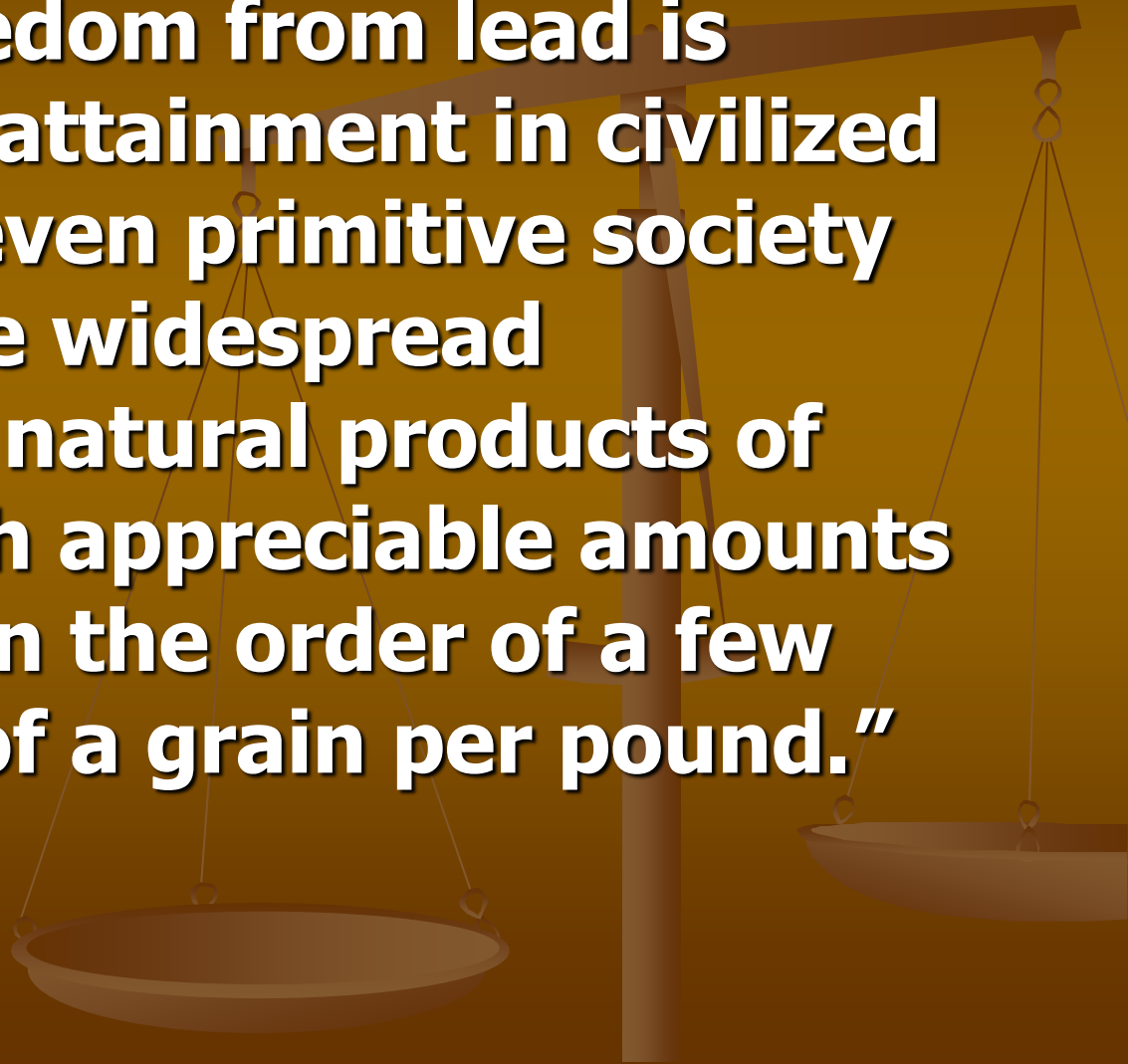
FDA's Early History of Regulation of Lead in Food

- **First extensive testing of foods for lead contamination was in the 1930s.**
- **Many foods found to have “small” amounts of lead**
- **Very few findings of problematic levels**



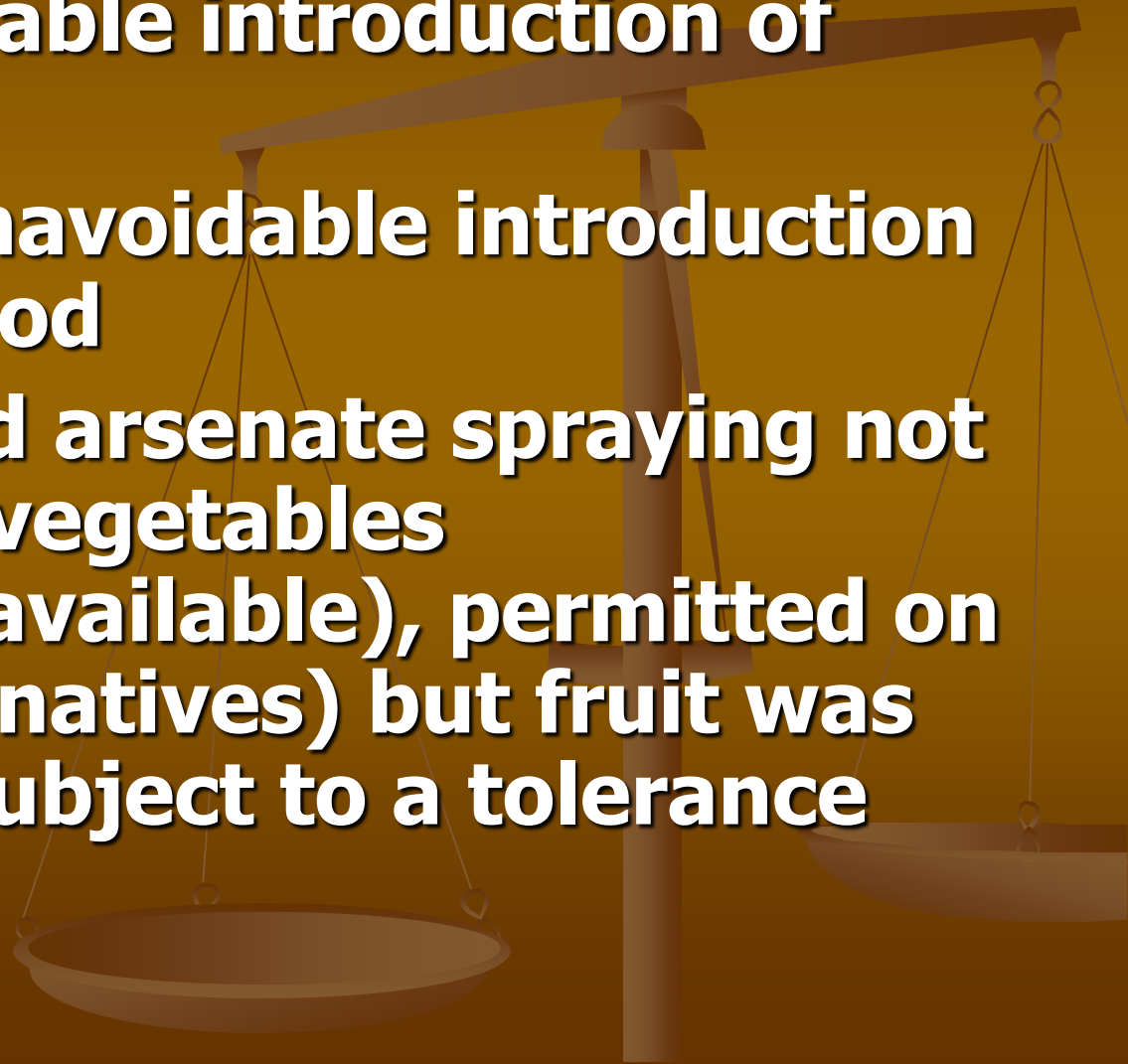
From August 1935 FDA Report

- **“Absolute freedom from lead is impossible of attainment in civilized and perhaps even primitive society because of the widespread occurrence in natural products of minute though appreciable amounts of this metal in the order of a few thousandths of a grain per pound.”**

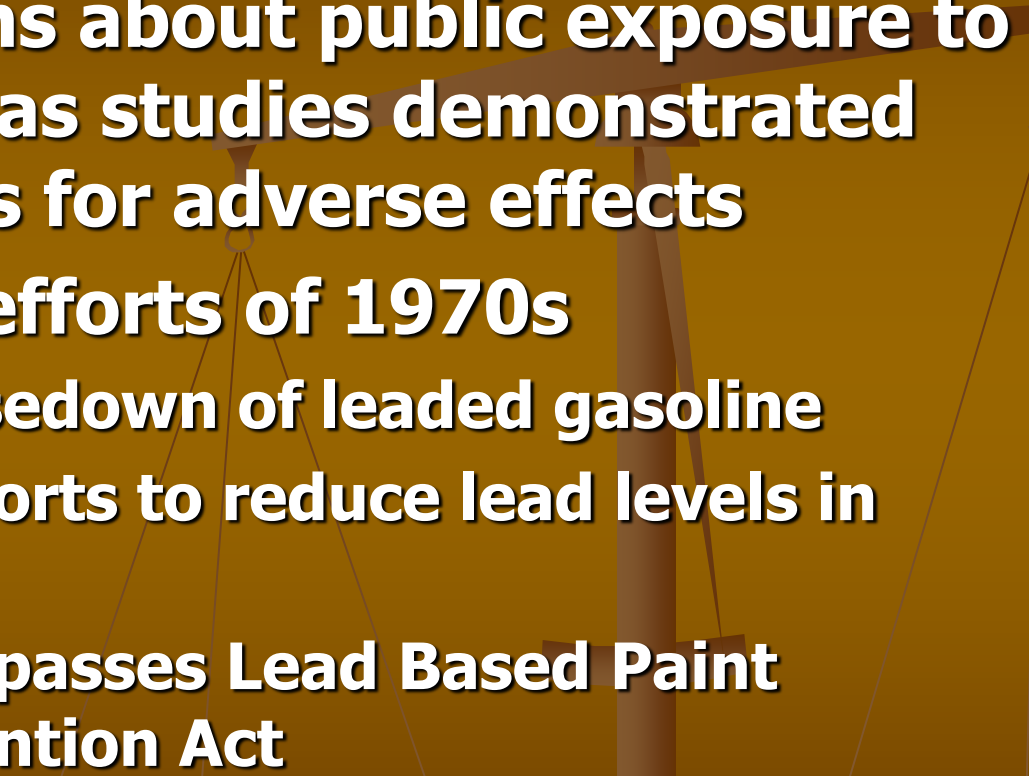


Foundational FDA Policy— Remains to This Day

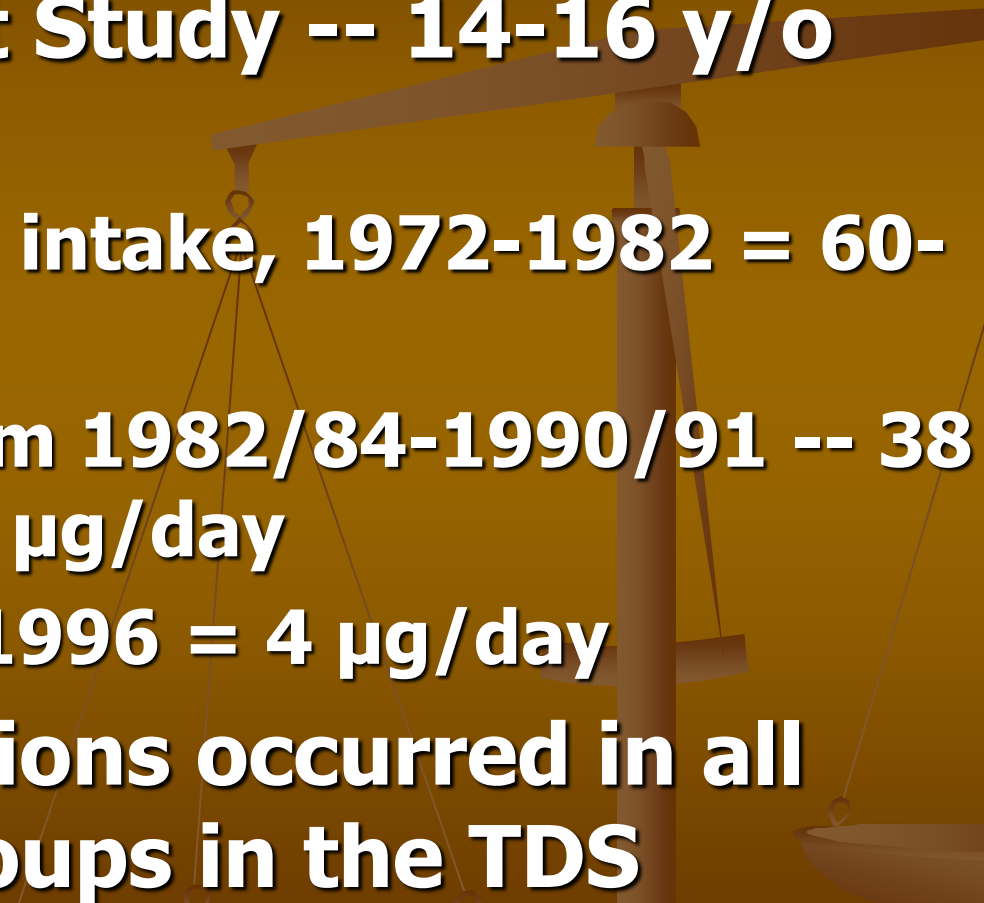
- **Prevent avoidable introduction of lead into food**
- **Control the unavoidable introduction of lead into food**
- **Example: Lead arsenate spraying not permitted on vegetables (alternatives available), permitted on fruit (no-alternatives) but fruit was washed and subject to a tolerance**



Broad Based Lead Reduction Efforts in the 1970s

- **By 1970 concerns about public exposure to lead had grown as studies demonstrated lower thresholds for adverse effects**
 - **Lead reduction efforts of 1970s**
 - **EPA begins phasedown of leaded gasoline**
 - **FDA initiates efforts to reduce lead levels in canned foods**
 - **1971, Congress passes Lead Based Paint Poisoning Prevention Act**
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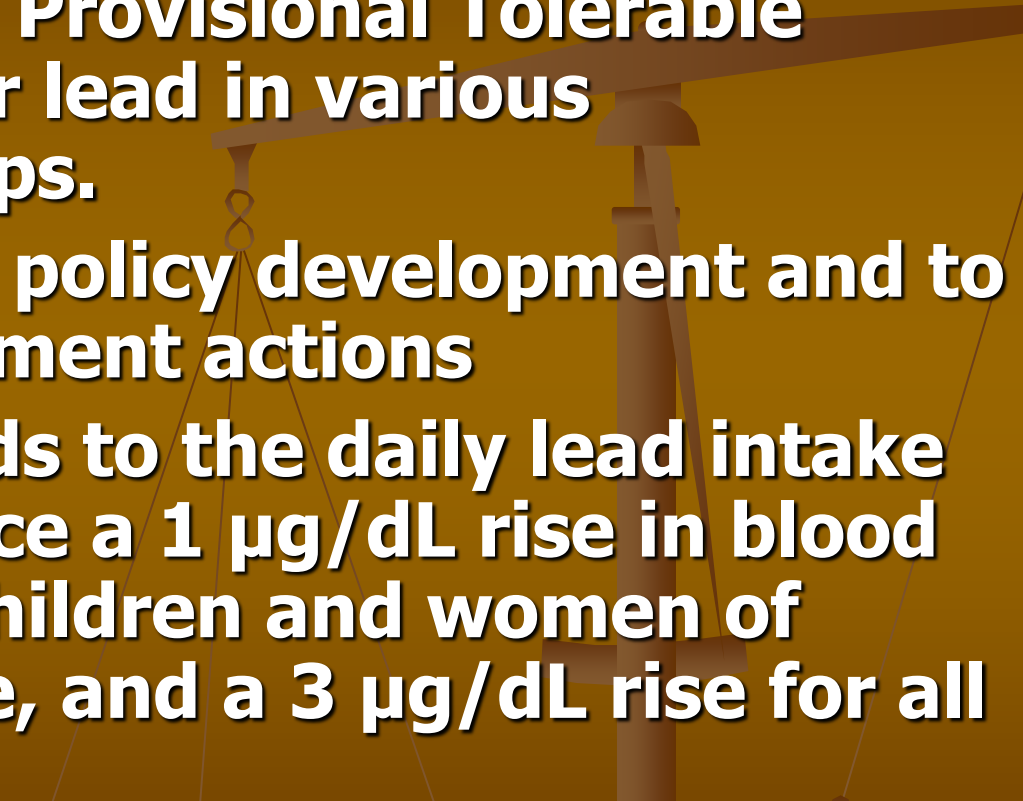
Progress in the 1970s and 1980s

- **FDA Total Diet Study -- 14-16 y/o males**
 - Est. daily lead intake, 1972-1982 = 60-90 µg/day
 - Reduction from 1982/84-1990/91 -- 38 µg/day to 3.2 µg/day
 - Intake 1991-1996 = 4 µg/day
 - **Similar reductions occurred in all population groups in the TDS**
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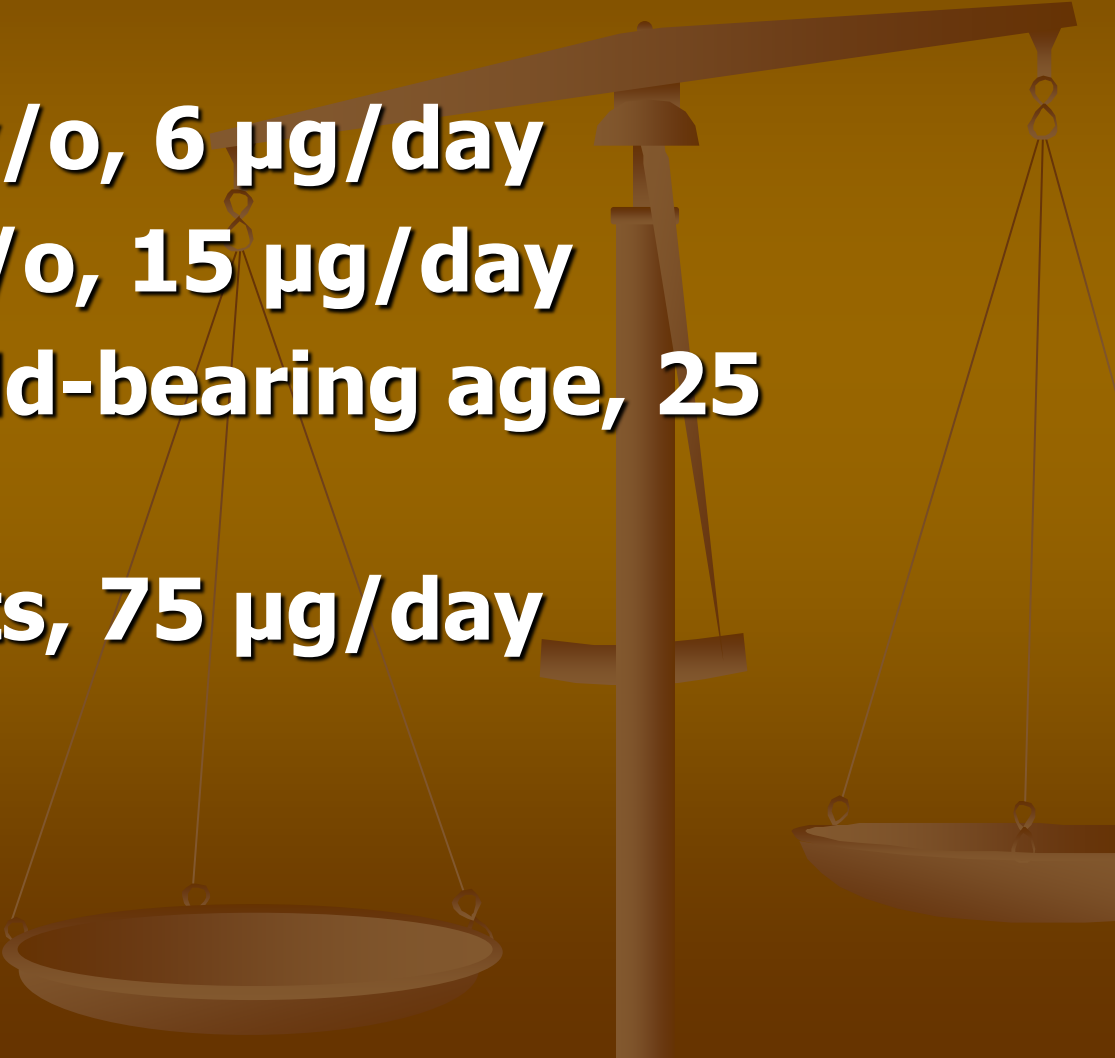
Lead Reduction Actions in 1990s

- **Spurred by findings in 1980s that lead exposure induced subclinical effects on cognitive development in children and fetuses.**
 - **10 $\mu\text{g}/\text{dL}$ established as blood lead level of concern by CDC**
 - **Recognition that there may not be a threshold**

Actions in 1990s -- PTDI

- **FDA established Provisional Tolerable Daily Intakes for lead in various population groups.**
 - **PTDI is used for policy development and to support enforcement actions**
 - **PTDI corresponds to the daily lead intake that would induce a 1 $\mu\text{g}/\text{dL}$ rise in blood lead levels for children and women of childbearing age, and a 3 $\mu\text{g}/\text{dL}$ rise for all other adults.**
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Actions in 1990s -- PTDI

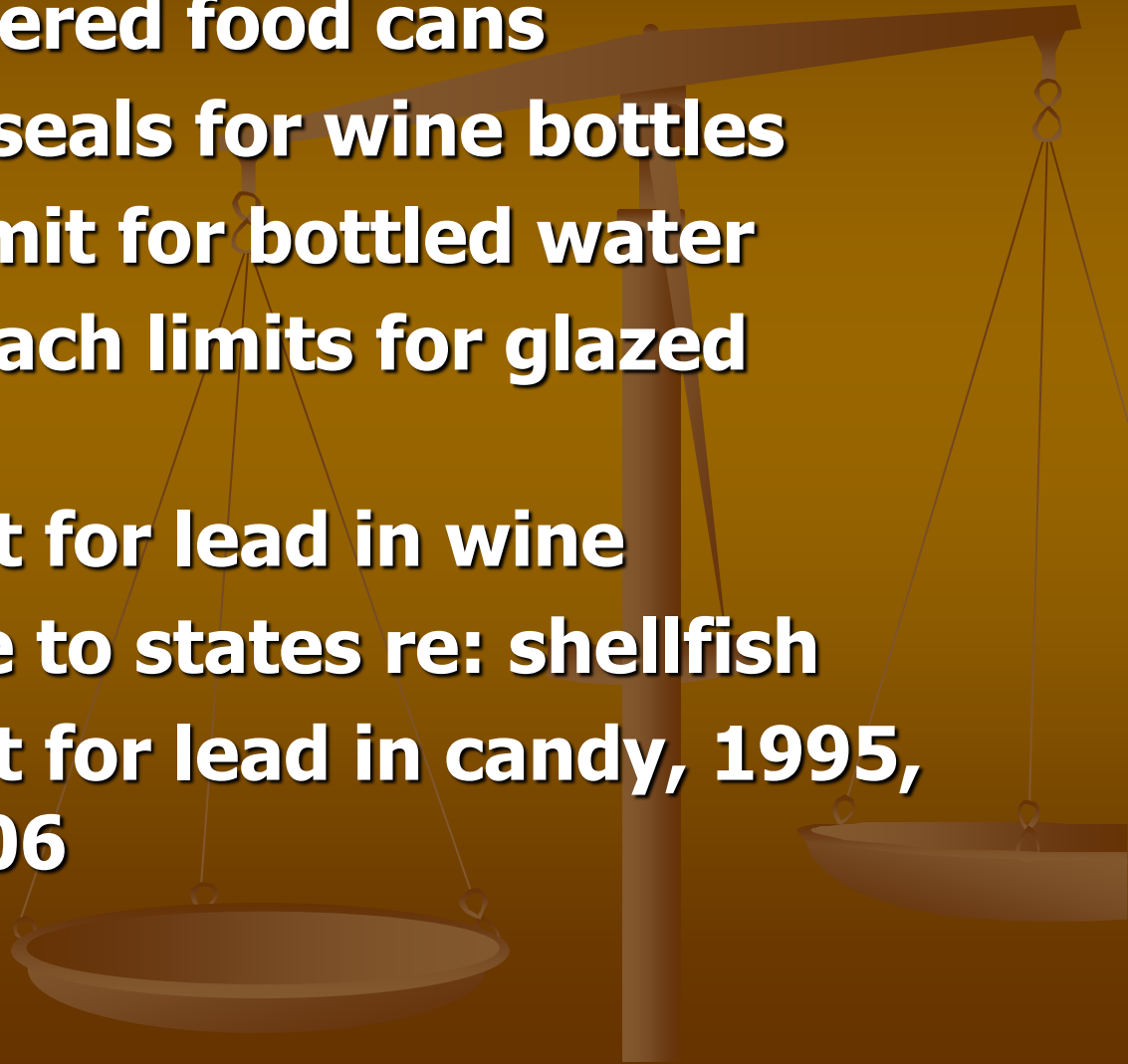
- **Children < 7 y/o, 6 µg/day**
 - **Children >7 y/o, 15 µg/day**
 - **Women of child-bearing age, 25 µg/day**
 - **All other adults, 75 µg/day**
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Most Recent Published TDS vs PTDI

- Current dietary lead intakes as measured by TDS for all population groups are between 1-5%, and 6-23% of PTDI
- Current dietary lead exposure for “general population” likely reflects background presence of lead in food and is low with respect to PTDI

Actions in 1990s

- **Ban of lead soldered food cans**
- **Ban of lead foil seals for wine bottles**
- **Lowered lead limit for bottled water**
- **Lowered lead leach limits for glazed ceramicware**
- **Established limit for lead in wine**
- **Issued guidance to states re: shellfish**
- **Established limit for lead in candy, 1995, tightened in 2006**



Current Concerns

- **Incidents of elevated lead levels in food and food related lead poisonings still occur.**
 - **Poorly fired traditional Mexican pottery, ongoing**
 - **Samovar (urn) from Iran used to prepare infant formula, tea – mother and infant, MA 2002**
 - **An adulterated Iraqi spice – 9 members of an extended family, MI 1998**
 - **Chili and salt containing Mexican candy, 1995-2006**

Current Concerns/Challenges

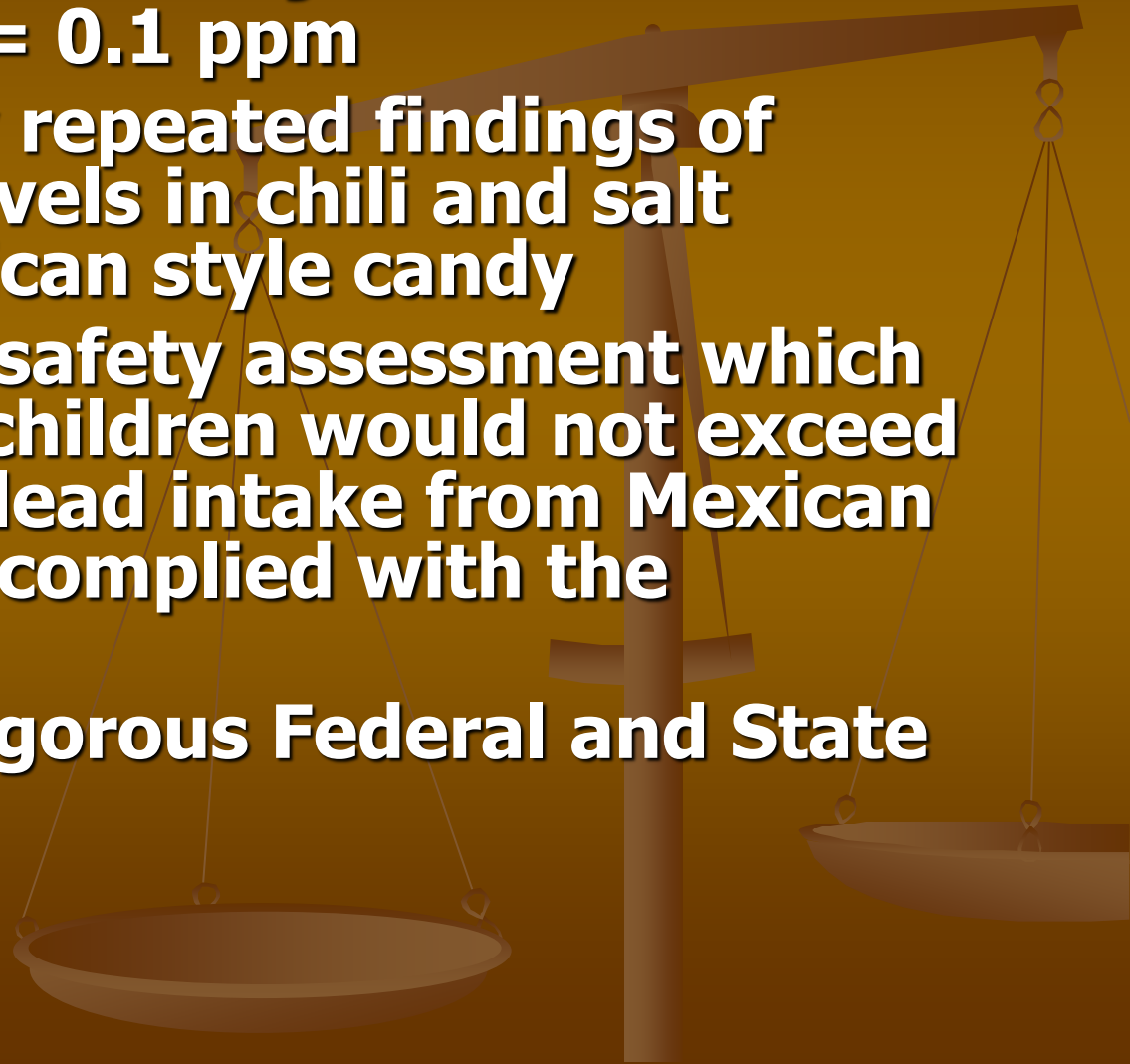
- **New type of challenge -- predominantly imports (era of global food trade)**
 - **Products may not be formally imported, not readily monitored at import -- samovar**
 - **Manufacturing methods may be culturally rooted in source countries – trad. pottery**
 - **Producers not necessarily available to partner with government in reductions efforts like automakers, can makers in 1970s**
 - **Lack of understanding of foreign production practices**

Current Concerns

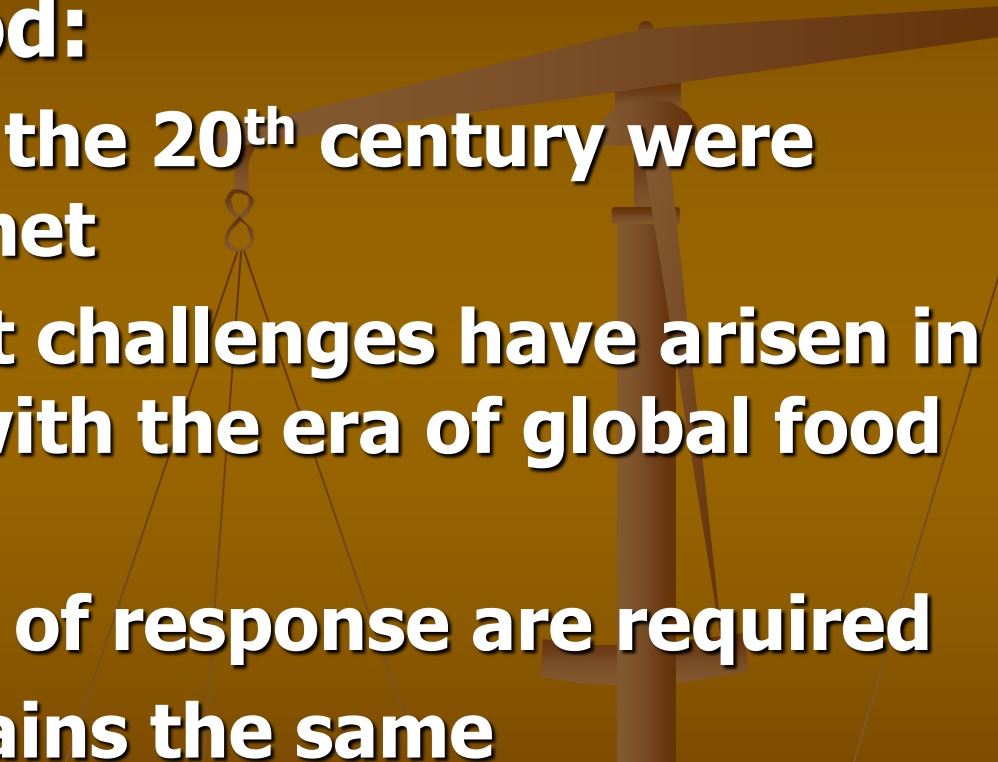
- **New types of challenges means that new types of responses will be necessary**
 - Targeted health risk communication outreach – 2007 Joint State-Federal project in SW U.S. focusing on traditional Mexican pottery
 - Certification by third parties in the country of origin, Chinese ceramicware
 - FDA offices abroad, e.g., China
 - New regulations/guidance

2006 Guidance Level for Lead in Candy

- Guidance level = 0.1 ppm
- Necessitated by repeated findings of elevated lead levels in chili and salt containing Mexican style candy
- Supported by a safety assessment which estimated that children would not exceed 1.3-2.3 $\mu\text{g}/\text{day}$ lead intake from Mexican style candy if it complied with the guidance level.
- Supported by vigorous Federal and State enforcement



Conclusion

- **For lead in food:**
 - **Challenges of the 20th century were successfully met**
 - **New/different challenges have arisen in 21st century with the era of global food trade**
 - **New methods of response are required**
 - **Goal still remains the same**
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Foundational FDA Policy— Remains to This Day

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- **Control the unavoidable introduction of lead into food**

